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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,139	11/20/2001	Mark Thiede	640100-420	9767

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/830,139	**Applicant(s)** THIEDE ET AL.	
	Examiner Joseph T. Woitach	**Art Unit** 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *6-8*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Joel Woitach
AU 1632

Continuation of 3. NOTE: The amendment to "consisting essentially of" alters the scope that requires a new search and consideration of the relevant art. Further, for new matter considerations, a review of the specification for the support would be required, and if supported to determine what is essential or what would materially change the composition that is administered encompassed by the claims-and its ultimate affect in practicing the method. The amendments appear to be made to address art rejections, however raise possible 112 issues that would require further consideration.

Continuation of 11. does NOT place the application in condition for allowance because:

With respect to arguments regarding the art rejections, the amendments to the claims have not been entered so the rejection stands for the reasons of record.

With respect to the rejection made under 112 and 101, Applicants comments and arguments that mesenchymal cells engraft when implanted has been acknowledged. However the basis of the rejection is not whether cells will implant into a subject, as this is effetively acknowledged by the rejections made under 35 USC 102, Rather, the considerations and examinations of the claimed invention under 112 and 101 is directed to the intended use taught by the present specification which is for the potential treatment of a subject.. Besides basis research, there are no other art accepted reasons for implanting mesenchymal stem cell in utero that are taught in the specification or that have been made of record, accordingly, the examination for the breadth of the claims to provide any benefit to a subject have been considered. It is noted that the claims simply recite delivery, but as noted throughout prosecution, the only reason for such a delivery supported by the present specification is for treatment. With respect to treatment, Applicants argue as supported by the specification that transplanted cells will act as a resevoir. This has not been found convincing for several reasons. First, cells implanted in utero generate a chimeric animal/subject-so at best a mixture of implanted cells and cells that are to be remedied by the implanted cells are present. Furhter, in the formation of a chimeric animal there is no control where the implanted cells will go or finally reside in a subject that one would believe that any treatment would be affected. Second, the implanted cells differentiate into multiple lineages, and in addition to not be present in the proper location do not necessarily serve as a resevoir. Finally, even if the implanted cell finds a proper location effective to "treat" a subject, the specific diseases contemplated would not be remedied by the proposed method because the presence of the endogenous cells providing for example aberrant forms of collagen would dominate over the presence/production of abnormal proteins.

Continuation of 13. Other:

The final action indicated that the application was not in sequence compliance, and that a complete response required submission of the necessary materials to make the applications compliant with 37 CFR 1.821-1.825 (see page 3 0f th efinal office action) .